

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

Dean Langford and Nancy Langford,
husband and wife,

Plaintiffs,

v.

Zimmer, Inc. and Zimmer Holdings, Inc.,

Defendants.

Case No: 03-12245-RCL

**REPLY IN SUPPORT OF
MOTION TO AMEND**

ORAL ARGUMENT REQUESTED

INTRODUCTION

Contrary to Defendants' assertions, Plaintiffs' motion to amend is neither unduly delayed nor does it present claims preempted by the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act (FDCA), and Plaintiffs' amendments should be allowed.

FACTS

As Plaintiffs discussed in their Motion to Amend, there are references within Mr. Langford's medical files to potential problems with other Zimmer products used in Mr. Langford's hip replacement, as well as to loosening of Mr. Langford's Centralign implant far before the implant was replaced. Before adding claims relating to these other devices and the premature loosening, however, Plaintiffs wished to conduct discovery to gain additional facts regarding these devices. In accordance with this intent, Plaintiffs' counsel suggested that the date for amendment of the pleadings fall at the close of discovery. However, Defendants suggested an early date. This Court selected a date for amendment of the pleadings at the outset of discovery. In that way, the parties would be able to conduct discovery, having each parties' claims in mind. Plaintiffs timely filed their motion to amend in accordance with this date.

ARGUMENT

Defendants' argument that Plaintiffs' motion to amend should be denied because it is unduly delayed is directly in conflict with the law of this Circuit. Relying on a decision from the District of Kansas, Defendants claim that undue delay is sufficient to bar Plaintiffs' amendments without any showing of prejudice to the Defendants. Def. Br. at 6. This is not the law of the First Circuit. Rule 15 explicitly states that "leave [to amend] shall be freely given" and consistent with that direction, the First Circuit has held that amendments should be allowed "[a]bsent futility, undue delay and undue prejudice." Fed. R. Civ. P. 15(a); *Vargas v. McNamara*, 608 F.2d 15, 18 (1st Cir. 1979). However, a motion to amend should not be denied "solely on the basis of delay." *Greenberg v. Mynczywor*, 667 F. Supp. 901, 905 (D.N.H. 1987). Instead, "a district court must consider prejudice to the opposing party." *Id.* Thus a court "may not deny an amendment solely because of delay and without consideration of the prejudice to the opposing party." *Tingley Systems, Inc. v. CSC Consulting, Inc.*, 152 F. Supp. 2d 95, 116 (D. Mass. 2001) (citing *Hayes v. New England Millwork Distributors, Inc.*, 602 F.2d 15, 19 (1st Cir. 1979)).

Plaintiffs' amendments are not unduly delayed, and more importantly, Defendants have not shown, or even argued, that they will suffer any prejudice if the amendments are allowed. Upon learning of the date set for amendment of pleadings, Plaintiffs promptly conferred with Defendants to agree to the amendments and, when Defendants did not stipulate, timely filed their motion to amend. Plaintiffs' amendments are proposed before any discovery has been initiated, and are in accordance with this Court's scheduling Order. In addition to these facts, federal courts have routinely determined that similarly-timed amendments, and even amendments brought far later and further into the litigation process, were not unduly delayed. *See Middle*

Atlantic Utilities Co. v. S.M.W. Development Corp., 392 F.2d 380, 384 (2nd Cir. 1968) (three year delay between filing of complaint and motion to amend insufficient to deny amendment). More importantly, Defendants have not alleged that they would suffer any prejudice by Plaintiffs' amendments, and indeed they will not. This litigation is in its early stages, and discovery has yet to commence. Defendants have ample time and opportunity to fully discover and explore the bases behind Plaintiffs' amendments, and no prejudice will result from allowing Plaintiffs to amend at this early stage in the litigation.

Defendants' alternative argument for denying Plaintiffs' motion to amend is also based on an incorrect statement of the law. Defendants argue that Plaintiffs' proposed amendment to add a cause of action under Mass. Stat. Gen. Ch. 93A ("Chapter 93A") should be denied because it would be "futile." Def. Br. at 4. Defendants state that Plaintiffs' claim is preempted by Section 360k(a) of the MDA, and cite a number of decisions rendered before the Supreme Court's decision in *Medtronic, Inc. v. Lohr* to support their claim. Def. Br. at 4-5. Defendants then, in a footnote, state that although the *Medtronic* decision held that "certain" state law claims were not preempted by the MDA, *Medtronic's* holding is limited to state common law claims. Defendants also state that no First Circuit decision had applied *Medtronic's* holding to Chapter 93A, and therefore that Chapter 93A claims remained preempted. Def. Br. at 5 n.2.

Defendants' argument is erroneous. *Medtronic* drastically changed the law of preemption under the MDA, effectively overruling previous First Circuit precedent, including most portions of the cases cited by Defendants, which provided blanket preemption of state statutory and common law relating to class III medical devices. Instead of embracing blanket preemption, *Medtronic* held that preemption under Section 360k(a) may "occur only where a particular state requirement threatens to interfere with a specific federal interest." *Medtronic v. Lohr*, 518 U.S.

470, 500 (1996). In 1999, three years after the *Medtronic* decision, this Court specifically addressed whether Section 360k(a) preempted a plaintiff's Chapter 93A claim that the manufacturer of a class III medical device had engaged in unfair and deceptive trade practices. *Haidak v. Collagen Corp.*, 67 F. Supp. 2d 21, 34 (D. Mass. 1999). The Court first noted that under the MDA and the *Medtronic* decision, "a party claiming preemption still 'must demonstrate that "there is a conflict between the state and federal regulations of the medical devices which threatens to interfere with a specific federal interest.'"" *Id.* at 33 (citations omitted). Then, specifically addressing Chapter 93A, the Court held that "Congress has spoken with unmistakable clarity that Section 360k(a) 'does not preempt State or local requirements of general applicability where the purpose of the requirement relates... to unfair trade practices in which the requirements are not limited to devices.'" *Id.* at 34. Accordingly, this Court held that the plaintiff's Chapter 93A claim was not preempted. *Id.* Plaintiffs' Chapter 93A claim is likewise not preempted. Defendants have made no showing of a specific conflict between state and federal laws to justify their claim of preemption and, as the *Haidak* decision observes, no such conflict exists. Plaintiffs' proposed amendments are not futile and should be allowed.

CONCLUSION

Defendants have misstated First Circuit law in an attempt to argue that Plaintiffs' motion to amend is untimely and preempted. First Circuit law does not support either of these propositions. Plaintiffs' amendments are timely, in accordance with this Court's scheduling Order, and Defendants have not argued that any prejudice would result from their allowance. Further, Plaintiffs' proposed claim under Chapter 93A is not preempted according to this Court's post-*Medtronic* decision. Accordingly, Plaintiffs respectfully request that they be allowed to amend their complaint.

Dated this _____ day of August, 2004.

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